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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,261	07/06/2006	Francis J. Michon	13564-105030	3361

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EXAMINER
ARCHIE, NINA

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,261	MICHON, FRANCIS J.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *18-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2005 and 7/6/2006* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

4. The information disclosure statement filed on 12/21/2005 and 7/6/2006 has been considered on. Initialed copy is enclosed.

Election/Restrictions

5. Applicant's election without traverse of Group I claims 1-17 is acknowledged.

Claim 18-28 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II (claims 18-22 and 25-27), Group III (claim 23), and Group IV (claim 28), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on 1/22/2008.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2, 6-10, 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Porro et al US 20060165730 (US Filing Date May 7, 2003).

Claims 1-2, 6-10, 12-17 are drawn to an immunogenic conjugate comprising group Y meningococcal polysaccharide covalently coupled to polymeric carrier, including O-deacetylated O-acetyl-positive group Y meningococcal polysaccharide or a fragment thereof, wherein the degree of de-O-acetylation is greater than 80%, for use as a vaccine against N. meningitidis infection.

Porro et al teach that “Ps structure are conveniently represented by the O-acetyl free oxidryl residues” and that “de-O-acetylation can be selectively and quantitatively achieved therefore Porro et al anticipate the degree of de-O-acetylation is greater than 80%, for use as a vaccine against N. meningitidis infection (see [0025] and [0027]). Porro et al teach an immunogenic conjugate comprising group Y meningococcal polysaccharide covalently coupled to polymeric carrier, including O-deacetylated O-acetyl-positive group Y meningococcal polysaccharide or a fragment thereof, wherein the degree of de-O-acetylation, characterized in the degree of de-O-acetylation is 100%

(see abstract, claims, see [0025] and [0027], steps 1-4). Porro et al teach a conjugate product comprising a de-O-acetylated meningococcal Y polysaccharide conjugated to a carrier protein, wherein the carrier protein is a bacterial toxin or toxoid, wherein the bacteria toxin or toxoid is tetanus ([0043]), wherein the modified meningococcal Y polysaccharide is as defined in claim 2. Porro et al teach a vaccine, wherein the bacterial toxin or toxoid is tetanus, which comprises an adjuvant, wherein the adjuvant is aluminum hydroxide (see [0061]-[0062], which is adapted for administration by injection, wherein the conjugated material comprises a polysaccharide as defined in claim 2 (see abstract, claims).

7. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michon et al WO 2000/10599 Date March 2, 2000 in view of Tai et al WO 1994/05325 March 17, 1994 and Hronowski et al "Abstracts of the General Meeting of the American Society for Microbiology Vol. 93, 1993 page 155, XP009040462 & 93rd General Mtg. of the American Society for Microbiology; Atlanta Georgia, USA; May 16-20, 1993 Issn: 1060-2011.

Claims 1-17 are drawn to an immunogenic conjugate comprising group Y meningococcal polysaccharide covalently coupled to polymeric carrier, including O-deacetylated O-acetyl-positive group Y meningococcal polysaccharide or a fragment thereof, wherein the degree of de-O-acetylation is greater than 80%, for use as a vaccine against N. meningitidis infection.

Michon et al teach a polysaccharide-protein conjugate comprising an N-propionated polysaccharide (derived from a Meningococcus group selected from the group consisting of group Y, group C, group W135, and combinations there-of: directly conjugated to a protein such as tetanus toxoid and diphtheria toxoid at the B-position of the propionate moiety. Michon et al teach a vaccine comprising the conjugate and a method of immunizing a mammal comprising administering said vaccine. Michon et al teach a polysaccharide is de-N-acetylated by base hydrolysis using e.g. 2N NaOH, and re-N-acylated (see claims, page 6, lines 29-33; page 7, line 24 to page 8, line 10), (page 17, line 27; page 19, line 16), (page 8, line 24 to page 9, line 7). Michon et al

teach that a vaccine can comprise an adjuvant such as aluminum hydroxide (see page 13. lines 15-18), and is adapted for administration by injection (see page 13, and page 25).

Thus Michon et al teach an immunogenic conjugate comprising group Y meningococcal polysaccharide covalently coupled to polymeric carrier, group Y meningococcal polysaccharide, with a molecular weight average of a 10 kDa, 50kDa and 150 kDa. Furthermore Michon et al teach a polysaccharide that has been fragmented and wherein the size of the fragment contains between 5 repeating units (ca 2.5 kDa) and-200 repeating-unit's (ca 100 kDa) and a polysaccharide, that has been fragmented and wherein the size of the fragment contains between 20 repeating units (ca 10 kDa) and 40 repeating units (ca 20 kDa) as evidenced to the contrary.

However, Michon et al does not teach a conjugate and vaccine wherein the group Y meningococcal polysaccharide is de-O-acetylated greater than 80% and 100%.

Tai et al teach an immunogenic conjugate comprising a (fragmented) de-O-acetylated group C meningococcal polysaccharide in which at least 80% of the 7- and 8- groups of the sialic residues are hydroxyl groups or a fragment thereof, covalently coupled to a suitable carrier material or molecule (tetanus toxoid) (see Claims 1-10, 16), and a vaccine comprising said conjugate (see claim 19). Tai et al teaches a method of immunizing mammals against N. meningitides infection, comprising the step of administering to said mammals a therapeutically effective amount of said vaccine (see Claim 23). Tai et al teach de-acetylation is carried out under mild basic conditions, such as 0.01 to 0.5 N NaOH (see claim 11, page 5 lines 27-31).

Hronowski et al teach an immunogenic conjugate of N. meningitidis group C polysaccharide coupled to the Tetanus toxoid protein carrier, and its use as vaccine. Hronowski et al teaches that if the polysaccharide is de-O-acetylated, the quality of the immune response shifts such that superior levels of bactericidal antibodies are obtained when the vaccine is tested in mice (see abstract).

It would have been prima facie obvious at the time the invention was made to de-O-acetylate a polysaccharide as taught by Tai et al and thus make a constructional change in the conjugated polysaccharide to modify the invention with a group Y

meningococcal polysaccharide conjugated to a carrier protein as taught by Michon et al because Hronowski et al teach that if the polysaccharide is de-O-acetylated, the quality of the immune response shifts such that superior levels of bactericidal antibodies are obtained when the vaccine is tested in mice.

Status of the Claims

8. No claims are allowed.

Claims 1-17 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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